

What is claimed is:

Add D15
1. A device which is implantable in a living body for dispensing liquid medication into the living body, comprising:

a reservoir chamber which contains medication to be dispensed, and

means for maintaining the pressure within the reservoir chamber at a level below the pressure of the living body.

2. A device, as in claim 1, wherein the pressure maintaining means comprises:

a liquid-vapor pool contained within the reservoir chamber, wherein the proportion of liquid to vapor varies in response to variations in the amount of medication contained in the reservoir chamber, and

a flexible diaphragm which separates and interfaces the liquid-vapor pool and the medication in the reservoir chamber.

3. A device, as in claim 2, wherein the pressure maintaining means further comprises:

a fill switch means, located within the reservoir chamber, for indicating when the reservoir is full by a switch actuation resulting when the flexible diaphragm comes in contact with the pressure sensing switch means and when the pressure exerted by the flexible diaphragm on the pressure sensing switch means is at a pressure less than the ambient pressure of the living body.

4. A device, as in claim 3, further comprising:
means for generating a subcutaneous electrical
stimulation to the living body, having a leak
switch means for switching at a pressure slightly
higher than that of the fill switch means to
indicate that body fluids have leaked into the
reservoir chamber.

a 5. A device, as in claim 1, further comprising:
a liquid-containing antechamber, and

a reservoir inlet valve located between the ante-
chamber and the reservoir chamber, the reservoir
inlet valve being opened only when the pressure in
the antechamber exceeds the pressure in the reservoir
chamber by more than a predetermined differential.

6. A device, as in claim 5, wherein the volume of
the antechamber is less than 10% the volume of the
reservoir chamber.

a 7. A device, as in claim 5, further comprising:
an inlet filter means, interposed between the ante-
chamber and the reservoir chamber, for preventing
impurities in the antechamber from passing into the
reservoir when the reservoir inlet valve is opened
and for preventing medication from within the
reservoir from rapidly entering the body in the
event of a leak in the reservoir inlet valve.

8. A device, as in claim 5, wherein liquid to the
antechamber is provided by a pair of hypodermic needles

which penetrate through the skin, and wherein the antechamber further comprises a self-sealing septum through which the two hypodermic needles enter, the two hypodermic needles providing an entrance into and an exit from, respectively, the antechamber.

9. A device, as in claim 5, further comprising:
means for programmed pumping of fixed-volume
pulses of medication into the living body.

10. A device, as in claim 9, wherein the pumping
means comprises a mechanical resistance (R) and mechanical capacitance (C) circuit resulting in an exponentially
decaying outflow of medication for each fixed-volume pulse.

11. A device, as in claim 9 or 10, wherein the pumping
means comprises means for storing medication and mechanical
means for inhibiting the pumping means when the pressure
within the medication storing means exceeds a fixed level.

12. A device, as in claim 1, further comprising:
a vitreous carbon insert implanted under the skin
of the living body, and

a tube connecting the carbon insert to the
reservoir chamber,

wherein medication is entered into the reservoir chamber
from outside the living body via the carbon insert and
the connecting tube.

13. A device, which is implantable in a living body, for dispensing a liquid to the body, comprising:
a reservoir chamber for containing liquid to be dispensed,

a normally dry lining which surrounds the reservoir chamber and which becomes wet when medication leaks out of the reservoir chamber; when body fluid leaks into the device; or when medication leaks out of the reservoir chamber and body fluid leaks into the device, and

alarm means responsive to the wetting of the normally dry lining for indicating device leaks.

14. A device, as in claim 13, further comprising:
means for maintaining the pressure within the reservoir chamber at a level below the pressure of the living body.

15. A medication dispensing pump, which is implantable in a living body, comprising:
means for feeding to the body a pulse of medication the flow of which decays exponentially over time.

16. A medication dispensing pump, which is implantable in a living body, comprising:
means for storing medication in the pump,

a plate which comprises a wall of the ^{medication} ~~drug~~-storing means, the plate having a surface which is in contact with the medication in the storing means,

means for moving the plate in a direction which increases the volume of the medication storing means, and,

spring means for moving the plate in a direction which decreases the volume of the medication storing means, wherein the magnitude of spring force applied to and stored by the spring means increases as the volume of the medication storing means increases.

17. A pump, as in claim 16, further comprising: means for limiting the distance the plate can move in both the volume-increasing direction and the volume-decreasing direction.

18. A pump, as in claim 16, wherein the spring means is inhibited from moving the plate when the pressure (p) in the medication storing means exceeds the spring force (F) exerted on the spring means divided by the wetted area (A) of the surface of the plate, that is when $p > F/A$.

19. A pump, as in claim 16, wherein the volume-increase moving means comprises a pulsing coil that exerts a pulsing magnetic field, and wherein the plate comprises a permanently magnetized material.

20. A pump, as in claim 16, wherein the spring means and the plate comprise a bellows assembly.

21. A pump, as in claim 16, further comprising:
a reservoir which contains medication,

an interface pressure valve through which medication
enters the storing means from the medication reservoir,

an outlet chamber which opens to the living body, and

an outlet pressure valve located between the storing
means and the outlet chamber, wherein the plate
movement effected by the volume-increase moving
means causes the interface pressure valve to open and
medication to enter the storing means and wherein the
plate movement effected by the spring means causes
the interface pressure valve to close and the outlet
pressure valve to open and medication to enter the
outlet chamber as a pressure pulse.

22. A pump, as in claim 21, wherein the outlet
chamber comprises:

a an elastic wall having a fluidic capacitive
effect on liquid flow, and

a filter element through which liquid flow to
the living body is resisted,

wherein the elastic wall and filter comprise a fluid
resistance-capacitance arrangement with respect to the
flow of medication from the outlet chamber to the
living body.

23. A pump, as in claim 21, further comprising:
monitoring means in the outlet chamber which provides
an electrical signal in response to a pressure pulse
in the outlet chamber caused by the medication pump.

24. A pump, as in claim 23, wherein the monitoring
means comprises a pressure transducer.

25. A pump, as in claim 24, further comprising:
means for indicating when compression of the storing
means caused by the volume-decrease moving means is
not followed by a pressure transducer signal
corresponding to a pressure pulse of medication
into the outlet chamber.

26. A pump, as in claim 23 or 25, further comprising:
means for indicating when a pressure transducer
signal occurs without a previous contraction of the
storing means caused by the volume-decrease moving
means.

27. A programmable infusion system for providing
medication to a living body, comprising:
a power source which provides an alternating field
and a command source which provides radio command
signals, wherein the power source and the command
source are external to the living body, and
a hermetically sealed electronics section, implanted

within body and having a plurality of operational parameters, which comprises:

receiver means for receiving the radio command signals, and

means for supplying operating power to the receiver means from the alternating field provided by the power source.

~~Sub C-20~~

28. A programmable infusion system, as in claim 27, further comprising:

detector means for picking up signals corresponding to the alternating field and to the command signals from the power source and command source, respectively, and

a

a

full-wave rectifier means for converting the induced alternating field signal from the detector means into a d.c. power signal, wherein the full-wave rectifier means comprises the means for providing operating power to the receiver means.

C

29. A programmable infusion system, as in claim ⁷³21, further comprising:

C

C

command decoder means, connected to the output of the receiver means, for decoding the radio command signals into programmed infusion rate inputs and ~~safety check~~ inputs, and

a plurality of programmable rate memory units, each

of which is connected to receive and store a corresponding infusion rate input decoded from a command signal.

30. A programmable infusion system, as in claim 29, further comprising:

a plurality of limit control units, each of which provides a fixed rate limit, and

means for comparing each infusion rate input, stored in a programmable infusion rate unit, with a corresponding fixed rate limit.

31. A programmable infusion system, as in claim 30, further comprising:

means for generating a subcutaneous electrical stimulation alarm signal when any infusion rate input exceeds ^a its corresponding fixed rate limit.

32. A programmable infusion system, as in claim 30 or 31, further comprising:

~~means for pumping medication into the body,~~

pump coil means for communicating a signal to the medication pumping means, indicating that medication is to be pumped into the body, and

^a means for inhibiting the ^{medication} ~~drug~~ pumping means when the infusion rate input exceeds the fixed rate limit.

Sub C21

33. A programmable infusion system as in claim 32, further comprising:

means for recording the number of times and the corresponding times at occurrence at which the pumping means pumped over a fixed, running length of time.

34. A programmable infusion system, as in claim 32, further comprising:

a pulse rate detector comprising:

means for counting the number of times the pumping means ^{pump} over a fixed time period,

minimum rate memory means for storing a programmable input corresponding to a minimum medication infusion rate, and

means for comparing the number in the counting means with the minimum ^{medication} ~~drug~~ infusion rate ~~and~~.

~~means for providing a subcutaneous electrical stimulation alarm signal when the count in the counting means is less than the minimum medication infusion rate.~~

Sub C22

35. A programmable infusion system, as in claim 33, further comprising:

a telemetry output which is external to the body, and

an implanted telemetry transmitter for communicating signals representing the operational parameters and recording means output of the electronics section to the telemetry output.

36. A programmable infusion system, as in claim 35, wherein the signals representing the operational parameters comprise:

the infusion rate inputs in the programmable rate memory units, and

the output from the command decoder.

37. A programmable infusion system, as in claim 27, further comprising:

means, implanted in the body, for pumping medication into the living body, and

reservoir means, implanted in the living body, for supplying medication to the pump,

wherein the pumping means is connected to and controlled by the electronics section which electronics means disallows more than a preprogrammed medication dosage.

38. A programmable infusion system, as in claim 37, further comprising:

means, implanted in the body, for maintaining the pressure in the reservoir means below the pressure of the living body.

39. A programmable infusion system, as in claim 38, further comprising:

telemetry transmitter means, implanted in the living body, and telemetry output receiver means, external

to the living body, wherein the telemetry transmitter means provides a signal to the telemetry output receiver means when the pressure in the reservoir means exceeds a threshold level.

40. A programmable infusion system, as in claim 39, wherein the threshold level is determined by the ambient pressure of the living body.

Sub C 13
41. A programmable infusion system, as in claim 40, further comprising:

means for generating a distinctive subcutaneous signal pattern for each of a plurality of safety and operational conditions in the system.

42. A patient interactive medication infusion system, comprising:

a patient programming unit, external to the patient's body, having a plurality of medication dose inputs selectable and requestable by the patient,

electrically activated means, implanted in the patient, for pumping medication into the patient, and

electronic control means, communicatively connected to and between the patient programming unit and the pumping means, for maintaining a history of pumped medication pulses and for activating the pumping means only for safe doses based on the maintained history.

43. A patient interactive medication infusion system, as in claim 42, wherein the patient programming unit comprises:

means for indicating to the patient if the medication dose input selected corresponds to a safe dose.

44. A patient interactive medication infusion system, as in claim 42, wherein the patient programming unit further comprises:

annunciator means and visual display means for providing information to the patient regarding previous selected medication doses, indicating whether a proper programming of dosage has been communicated to the implanted pumping means and for selectively providing information as to the time and amount of previously selected medication dosage.

45. A patient interactive medication infusion system, as in claim 42, further comprising:

limit control storing means for a hardwired limit and comparing dose inputs selected by the patient with the hardwired limit.

46. A patient interactive medication infusion system, as in claim 45, further comprising:

means for signalling the patient if a selected dose input exceeds the corresponding hardwired limit.

47. A method for filling an implanted medication dispensing device having a reservoir chamber, an antechamber, and an inlet pressure valve which interfaces the antechamber and the reservoir chamber, wherein the method comprises the steps of:

sensing the pressure in the antechamber,

determining from the sensed pressure there is pressure integrity in the antechamber, and

introducing the medication from a medication source external to the body into the antechamber only if there is pressure integrity within the antechamber.

48. A method, as in claim 47, comprising the further step of:

flushing the antechamber with a nontoxic solution prior to the sensing of pressure in the antechamber.

49. A method, as in claim 47 or 48 wherein the step of introducing the medication comprises the steps of:

flushing the antechamber with the medication,

forcing medication into the antechamber at a pressure sufficient to open the inlet pressure valve thereby connecting the antechamber to the reservoir chamber, and

filling the reservoir chamber with medication forced into the antechamber and through the inlet pressure valve until the pressure in the reservoir chamber reaches a predetermined pressure level.

50. A method, as in claim 49, wherein the step of
a introducing ^{medication} ~~drug~~ comprises the further steps of:
discontinuing the forcing of medication into the
antechamber when the pressure in the reservoir chamber
reaches the predetermined pressure level, and
flushing and filling the antechamber, at a pressure
below that required to open the inlet pressure valve,
a with the nontoxic solution after the forcing of ^{medication} ~~drug~~
is discontinued.

51. A method of programming a medication infusion
system, having an implanted memory rate unit and means for
inputting infusion commands from outside the living body
to the memory rate unit, comprising the steps of:
storing in the memory rate unit a first maximum value
of infusion pulses allowable during a short fixed
running length of time,
requesting infusion pulses of medication,
subtracting pulses from the maximum value as they
are requested, and
adding subtracted pulses as a short fixed running length
of time passes after the pulses are subtracted in
running integral fashion.

52. A method of programming a medication infusion system, as in claim 51, comprising the further steps of:
storing in the memory rate unit a second maximum value of infusion pulses allowable during a long fixed running length of time, ^{and adding and subtracting the} ~~adding and subtracting the~~ ^{pulses in running integral fashion,} ~~pulses in running integral fashion, and~~

a

53. A method of programming a medication infusion system, as in claim 51 or 52, further comprising the step of:

inhibiting the infusion of pulses when more than a maximum value of pulses is to be subtracted during its corresponding fixed, running length of time.

54. A method of programming a medication infusion system, as in claim 53, further comprising the steps of:
limiting the total number of pulses subtracted during a fixed, running length of time to its corresponding maximum value,

storing pulse requests related to pulses that are inhibited, and

executing stored pulses to raise the number of executed pulses during the fixed, running length of time to a number no greater than the maximum value.

Add B.7

add 24